

(8) *Reporting of data and evaluation of results.* The protocol should explain how data obtained are to be reported and summarized. The criteria for evaluating the results and the basis for conclusions to be drawn should be explained.

(9) *Conclusions.* The protocol should provide for a statement of what the data obtained demonstrate and what conclusions were reached.

## PART 500—RULES OF PRACTICE

Sec.

500.1 Definitions.

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AUTHORITY: 21 U.S.C. 451–470, 601–695; 7 U.S.C. 450, 1901–1906; 7 CFR 2.18, 2.53.

SOURCE: 64 FR 66546, Nov. 29, 1999, unless otherwise noted.

### § 500.1 Definitions.

(a) A “regulatory control action” is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.

(b) A “withholding action” is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process.

(c) A “suspension” is an interruption in the assignment of program employees to all or part of an establishment.

### § 500.2 Regulatory control action.

(a) FSIS may take a regulatory control action because of:

- (1) Insanitary conditions or practices;
- (2) Product adulteration or misbranding;

(3) Conditions that preclude FSIS from determining that product is not adulterated or misbranded; or

(4) Inhumane handling or slaughtering of livestock.

(b) If a regulatory control action is taken, the program employee will immediately notify the establishment orally or in writing of the action and the basis for the action.

(c) An establishment may appeal a regulatory control action, as provided in §§ 306.5 and 381.35 of this chapter.

### § 500.3 Withholding action or suspension without prior notification.

(a) FSIS may take a withholding action or impose a suspension without providing the establishment prior notification because:

(1) The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 602;

(2) The establishment does not have a HACCP plan as specified in § 417.2 of this chapter;

(3) The establishment does not have Sanitation Standard Operating Procedures as specified in §§ 416.11–416.12 of this chapter;

(4) Sanitary conditions are such that products in the establishment are or would be rendered adulterated;

(5) The establishment violated the terms of a regulatory control action;

(6) An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS employee; or

(7) The establishment did not destroy a condemned meat or poultry carcass, or part or product thereof, in accordance with part 314 or part 381, subpart L, of this chapter within three days of notification.

(b) FSIS also may impose a suspension without providing the establishment prior notification because the establishment is handling or slaughtering animals inhumanely.

### § 500.4 Withholding action or suspension with prior notification.

FSIS may take a withholding action or impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance because:

(a) The HACCP system is inadequate, as specified in § 417.6 of this chapter,